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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/769,021	01/30/2004	Robert R. Whittle	5573-115IP7CT7	9712
20792 7590 09/14/2007 MYERS BIGEL SIBLEY & SAJOVEC PO BOX 37428 RALEIGH, NC 27627			EXAMINER SPIVACK, PHYLLIS G	
			ART UNIT 1614	PAPER NUMBER
			MAIL DATE 09/14/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/769,021	<b>Applicant(s)</b> WHITTLE ET AL.	
	<b>Examiner</b> Phyllis G. Spivack	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 65-84 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 65-84 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>7-20-04; 2-22-07</u> . | 6) <input type="checkbox"/> Other: _____  |

A request for continued examination under (RCE) 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on February 22, 2007 has been entered.

Claims 65-84 remain under consideration.

An Information Disclosure Statement filed February 22, 2007 is acknowledged and has been reviewed. It is noted eighteen references were scanned on March 20, 2007 and are part of the record. It appears these documents are part of the Information Disclosure Statement filed July 20, 2004. The present Examiner has reviewed these newly scanned documents to the extent each reference is presented in the English language and has initialed Form PTO-1449 that was submitted on July 20, 2004.

A complete list of all co-pending and related applications and issued patents for the inventive entity is requested when Applicants respond to this Office Action.

The abstract of the disclosure is objected to because it is not drawn to the subject matter presently under consideration. Correction is required. See MPEP § 608.01(b).

Claims 65-84 were rejected on the ground of nonstatutory double patenting over claims 1-68 of U. S. Patent No. 6,369,087 in the last Office Action. It was asserted the subject matter claimed in the instant application is fully claimed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, i.e., a composition comprising the 5-methoxy and/or 6-methoxy enantiomers of omeprazole.

Claims 65-84 were rejected on the ground of nonstatutory double patenting over claims 1-12 of U. S. Patent No. 6,262,085 in the last Office Action. It was asserted the subject matter claimed in the instant application is fully claimed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, i.e., a composition comprising the 5-methoxy and/or 6-methoxy enantiomers of omeprazole.

Claims 65-84 are rejected on the ground of nonstatutory double patenting over claims 1-17 of U. S. Patent No. 6,706,737 in the last Office Action. It was asserted the subject matter claimed in the instant application is fully claimed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, i.e., a composition comprising the 5-methoxy and/or 6-methoxy enantiomers of omeprazole.

Claims 65-84 were rejected on the ground of nonstatutory double patenting over claims 1-30 of U. S. Patent No. 6,667,321 in the last Office Action. It was asserted the subject matter claimed in the instant application is fully claimed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, i.e., a composition comprising the 5-methoxy and/or 6-methoxy enantiomers of omeprazole.

Claims 65-84 were rejected on the ground of nonstatutory double patenting over claims 1-24 of U. S. Patent No. 6,444,689 in the last Office Action. It was asserted the subject matter claimed in the instant application is fully claimed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, i.e., a composition comprising the 5-methoxy and/or 6-methoxy enantiomers of omeprazole.

Claims 65-84 were rejected on the ground of nonstatutory double patenting over claims 1-5 of U. S. Patent No. 6,667,324 in the last Office Action. It was asserted the subject matter claimed in the instant application is fully claimed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, i.e., a composition comprising the 5-methoxy and/or 6-methoxy enantiomers of omeprazole.

Claims 65-84 were rejected on the ground of nonstatutory double patenting over claims 1-45 of U. S. Patent No. 6,653,329 in the last Office Action. It was asserted the subject matter claimed in the instant application is fully claimed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, i.e., a composition comprising the 5-methoxy and/or 6-

methoxy enantiomers of omeprazole.

Applicants have again reiterated their intention to submit a terminal disclaimer upon indication of allowable subject matter in the present application.

Because no indication of allowable subject matter is presented, the rejections of record drawn to nonstatutory double patenting are maintained.

Claims 65-84 were provisionally rejected on the ground of nonstatutory double patenting over claims 1-101 of copending Application No. 10/855809 in the last Office Action.

Because S.N. 10/855809 is abandoned, the rejection set forth supra is moot.

Applicants' arguments with respect to claims 65-84 that were rejected under 35 U.S.C. 102(b) in the last Office Action, have been considered but are moot in view of the new ground of rejection.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 65-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Von Unge, S., WO 95/32957, in view of Alminger et al., U.S. Patent 5,021,433.

Omeprazole is well established in the prior art as an effective gastric acid secretion inhibitor and is useful as an antiulcer agent (page 1, lines 14-15). As disclosed by Von Unge, separation of the enantiomers of omeprazole is known in the prior art and is described in J. Chromatography, 532 (1990), 305-19. As specifically required by instant claim 70, Von Unge teaches an "optically pure compound," which means one enantiomer is "essentially free" of the corresponding enantiomer. Both 5-

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methoxy- and 6-methoxy-enantiomers of omeprazole are disclosed in the reference on page 4, lines 15-25. Further, on page 9, line 8, dosage units for oral administration of the optically pure compound having an alkaline component, i.e., a magnesium cation, are disclosed, as required by instant claims 69, 74 and 79. On page 9, lines 19-20, an enterically coated capsule form is disclosed, as required by instant claims 66, 71 and 76. On page 9, lines 9-10, the active agent is disclosed to be up to 95% by weight of the preparation. The preparation of the 6-methoxy enantiomer is shown in Example 4, page 12. The claims differ in that Von Unge refers to ethyl carbonate derivatives of omeprazole.

However, Alminger teaches both the existence of pure enantiomers of omeprazole derivatives and equivalence of the position isomers, i.e., 5-methoxy and 6-methoxy, disclosed, *inter alia*, in column 29. See column 3, lines 29-31, as well as the last two structures at the bottom of column 7.

Further, Von Unge teaches these ethyl carbonate derivatives are metabolized into the corresponding compounds having a hydrogen atom in the N-1 position on the benzimidazole ring before exerting their effect.

Accordingly, one skilled in the art of formulation chemistry, in view of the teachings of the references cited above, would have been motivated to seek a pharmaceutical formulation comprising the optically pure form of 6-methoxy-2-[[*(S)*-(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfonyl]-1H-benzimidazole. Such would have been obvious in the absence of evidence to the contrary because, based on the asymmetric center of the sulfur atom of omeprazole and the established means of separation of the enantiomers, specifically obtaining an optically pure derivative of the 6-methoxy enantiomer is taught by Von Unge. Further, Von Unge's teaching that omeprazole having a hydrogen atom in the N-1 position on the benzimidazole ring is the active form of the drug provides motivation to seek an optically pure derivative of the 6-methoxy enantiomer to treat gastric acid related diseases.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

September 11, 2007



Phyllis Spivack

**PHYLLIS SPIVACK  
PRIMARY EXAMINER**

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